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| LIST OF REFERENCES CITED BY APPLICANT(S) | | | | FILING DATE GROUP | | | | |
| TO THE PARTY OF | USB | several sheets if necessary |) | 31 October 1997 1615 | | | 5 | |
| MAD | | | υ. | S. PATENT DOCUMENTS | | | | |
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| | | | FORE | EIGN PATENT DOCUMENTS | | | | · |
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| | 3 | | . | | | | | |
| | | OTHER | DOCUMENT(S) (| Including Author, Title, Date, Pe | rtinent Pages, Etc.) | · · · · · · · · · · · · · · · · · · · | | |
| | 1 | | • | Blume, Ph.D. (Janu | ıary 27, 200 | 14) | | |
| CH | | - Subject to Prot | tective Orde | er | | | | |
| <u> </u> | 2 | Expert Report o | f Dr. Sergio | Fazio (February 4, | 2004) [Red | lacted Versi | on] | |
| İ | | - Subject to Prot | _ | | | | | |
| | 3 | Dahamal E | Danaud : 61 | D. Consta Fasta (As | | · · · · · · · · · · · · · · · · · · · | , | |
| | 3 | - Subject to Prof | • | Dr. Sergio Fazio (A) er | orii 2, 2004) | | | |
| | 4 | Expert Report o | f Dr. Sergio | Fazio Regarding | | | | |
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| | | - Subject to Prot | tective Orde | er | | | | |
| | 5 | Evnort Donort o | f Don W M | lartens (February 6 | 2004) [Pag | lacted Vers | ionl | |
| | | - Subject to Prof | | _ | , 2004) [Red | zacceu vers | ionj | |
| | 6 | Evnert Penart | f Don W M | lartens Regarding | | | | |
| | | | | lartens Regarding Lugust 20, 2004) [Re | edacted Ver | sion] | | |
| | | - Subject to Pro | | | | - | | |
| | - | W3 4 W3 4 | 6D 7 3 | | | 04) (D = 3 = . 4 | .3 77 | |
| | 7 | - Subject to Prot | | h R. Robinson (Feb er | ruary 5, 200 |) (Kedacte | xa ve | r510Nj |
| | | | | | | | | |
| | 8 | | | h R. Robinson Rega | rding | | | |
| | | U.S. Patent No Subject to Prot | | | | | | |
| | | | | | | | | |
| 1 | 9 | _ | - | Thomas S. Foster, P | harm.D. (A | pril 2, 2004 |) | |
| V | | - Subject to Prot | tective Orde | er | | | | |
| | | L | | | | | | |

Casey Hagopai 5-31-2005

| C | H | 10 | Rebuttal Expert Report of Thomas S. Foster, Pharm.D. Regarding The '967 Patent (October 4, 2004) - Subject to Protective Order |
|---|---|-----|---|
| | 1 | 11. | Rebuttal Expert Report of James W. McGinity, Ph.D. (April 2, 2004) - Subject to Protective Order |
| | | 12 | Supplemental Rebuttal Expert Report of James W. McGinity, Ph.D. (August 18, 2004) - Subject to Protective Order |
| | | 13 | Rebuttal Expert Report of James W. McGinity, Ph.D. Regarding The '967 Patent (September 30, 2004) - Subject to Protective Order |
| | | 14 | Expert Report of Mark E. McGovern, M.D. (February 6, 2004) - Subject to Protective Order |
| | *************************************** | 15 | Expert Report of Mark E. McGovern, M.D. (August 20, 2004) - Subject to Protective Order |
| | | 16 | Expert Report of Frank M. Sacks, M.D. (April 2, 2004) - Subject to Protective Order |
| | | 17 | Expert Report of Frank M. Sacks, M.D. (August 20, 2004) - Subject to Protective Order |
| | | 18 | Rebuttal Expert Report of Mary Ann Tucker, Esq. (April 2, 2004) - Subject to Protective Order |
| | , | 19 | Rebuttal Expert Report of Mary Ann Tucker, Esq. Regarding The '967 Patent (October 1, 2004) - Subject to Protective Order |
| | | 20 | Carl J. Lavie, et al., Marked Benefit with Sustained-Release Niacin Therapy in Patients with Alsolated@Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease, Am. J. Cardiol. 1992:69:1083-1085 |
| | | 21 | Excerpts from the 1993, 2000, and 2002 editions of the Physician's Desk Reference |
| | | 22 | Niacin: Double-edged Sword for Lowering Cholesterol, Tufts University Diet & Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6 |
| | | 23 | Larsen, ML and Illingworth, DR, Drug Treatment of Dyslipoproteinemia, Med Clin N Am., 78:225-245 (1994) |
| V | , | 24 | Lavie, Letter to Editor, JAMA 1994; 272:513-515 |
| | | | |

| CH | 25 | Keenan, Letter to Editor, JAMA 1994; 272:513-515 |
|----------|----|---|
| <u> </u> | 26 | Shields & Beckmann, Letter to Editor, JAMA 1994; 272:513-515 |
| | 27 | Thomas N. Tozer, Clinical Pharmacokinetics Concepts and Applications (3d ed. 1995) at Chapter 9, p. 120 |
| | 28 | Excerpts from the United States Pharmacopeia (1995) |
| | 29 | Morgan & Capuzzi Abstract, Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin, Clinical Pharmacology & Therapeutics (February 1996) |
| | 30 | Morgan & Capuzzi Article, Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial, J. Cardiovasc. Pharmacol. Therapeut. 1(3):195-202 (July 1996) |
| | 31 | Capuzzi DM, et al., Efficacy and Safety of An Extended-Release Niacin (Niaspan): A Long-Term Study, Am J Cardiol. 1998;82:74U-81U |
| | 32 | Guyton JR, Advances in Dyslipidemia: Discussion Session II, Am J Cardiol, 1998: 82(12A): 85U-86U |
| | 33 | Knopp RH, et al., Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Give Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia, Metabolism 47:1097-1104 (1998) |
| | 34 | American Diabetes Association: Management of Dyslipidemia in Adults with Diabetes, Diabetes Care 21:179-182, 1998 |
| | 35 | Elam MB, et al., Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease, JAMA: 2000; 284:1263-1270 |
| | 36 | Kesala R, et al., Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patient (DP), Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000) |
| · | 37 | 2001 NCEP Report at VI-11, Table VI.2-3 |
| 1 | 38 | Wang, W. et al., Effect of Nicotinic Acid Administration on Hepatic Very Low Density Lipoprotein-Triglyceride Production, Am J Physiol Endocrinol Metab., 280:E540-E547 (2001) |

| CH | 39 | Smith SC, et al., AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update. AHA/ACC Scientific Statement, 1577-79 |
|----------|----|--|
| (| 40 | Tavintharan S and Kashyap M, The Benefits of Niacin in Atherosclerosis, Curr Athero. Reports 2001; 3:74-82 |
| | 41 | Meadows M., Serious Liver Injury: Leading Reason for Drug Removals, Restrictions, FDA Consumer Magazione, May-June 2001; http://www.fda.gov/fdac/features/2001/301_liver.html |
| | 42 | Grundy SM, et al., Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes. Arch Intern Med. 2002; 162: 1568-1576 |
| | 43 | American Diabetes Association: Management of Dyslipidemia in Adults with Diabetes, Diabetes Care 25:S74-S77, 2002 |
| | 44 | Pan J, et al., Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabetes, Diabetes, Obesity and Metabolism 4:255-261 (2002) |
| | 45 | Pan J, et al., Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes, Metabolism 51:1120-1127 (2002) |
| | 46 | Meyers CD, et al., Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia, Ann Intern Med. 2003; 139:996-1002 |
| | 47 | CDER Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (March 2003) |
| | 48 | American Diabetes Association: Dyslipidemia Management in Adults with Diabetes, Diabetes Care 27:S68-S71, 2004 |
| | 49 | Sample Kos Clinical Trial Medical Consent Form -Subject to Protective Order |
| I | 50 | Sample Kos Clinical Trial Investigator's Statement |